kuraray

K063593

FEB - 2 2007

Date: December 1, 2006

510(k) Summary

3-1. 510(k) owner (submitter)

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in U.S.	Koji Nishida KURARAY AMERICA INC. 600 Lexington Avenue, 26th Floor New York, NY 10022 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

3-2. Name of Device

1) Trade / Proprietary name	CLEARFIL MAJESTY Flow
2) Classification name	Tooth shade resin material (21 CFR section 872.3690. Product code: EBF)
3) Common name	Flowable restorative composite resin
4) Device listing number	R001413

3-3. Predicate device

1) TETRIC FLOW	510(k) Number:	K993783
	Product Code:	EBF (21 CFR Section: 872.3690)
	Applicant:	IVOCLAR NORTH AMERICA, INC.
2) CLEARFIL AP-X	510(k) Number:	K012740
	Product Code:	EBF (21 CFR Section: 872.3690)
	Applicant:	KURARAY MEDICAL INC.
3) EPRICORD	510(k) Number:	K033267
	Product Code:	EBF (21 CFR Section: 872.3690)
	Applicant:	KURARAY MEDICAL INC.
4) CLEARFIL SE BOND	510(k) Number:	K012442
	Product Code:	KLE (21 CFR Section: 872.3200)
	Applicant:	KURARAY MEDICAL INC.

3-4. Description of device

CLEARFIL MAJESTY Flow is a flowable, radiopaque restorative composite resin which provides true to life color matching, high polish ability and excellent physical properties, making it ideal for both anterior and posterior restorations. CLEARFIL MAJESTY Flow can be used alone or together with CLEARFIL AP-X and CLEARFIL MAJESTY Esthetic.

It is classified into tooth shade resin material (21 CFR section 872.3690, Product code: EBF) according to 21 CFR § 872 since it is composed of materials such as methacrylate monomers.

According to the applicable FDA recognized consensus standard, ISO 4049: 2000 "Dentistry - Polymer-based filling, restorative and luting materials", this device is classified into the following:

- Type 1: polymer-based filling and restorative materials;
- Class 2: materials whose setting is effected by light;
- Group 1: materials whose use requires the energy to be applied intra-orally.

3-5. Intended uses

CLEARFIL MAJESTY Flow is indicated for the following restorative applications:
- Direct restorations for anterior and posterior teeth (Class I – III, V cavities, cervical caries, root erosion)
- Cavity base / liner
- Intraoral repairs of fractured crowns / bridges / composite resin

The intended uses of CLEARFIL MAJESTY Flow are substantially equivalent to those included in the indications for use of TETRIC FLOW, the predicate device.

3-6. Technological characteristics of device

1) Safety

All the chemical ingredients of CLEARFIL MAJESTY Flow, the applicant device, have been used in the predicate devices indicating that the safety of the applicant device is substantially equivalent to the predicate devices.

2) Effectiveness / Performance

CLEARFIL MAJESTY Flow, the applicant device, is verified to comply with the requirements of the applicable FDA recognized consensus standard, ISO 4049: 2000 "Dentistry - Polymer-based filling, restorative and luting materials". As to compare with the predicate devices according to ISO 4049: 2000, both the applicant and the predicate device comply with ISO 4049: 2000 indicating that the applicant device is as effective as and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Koji Nishida
General Manager
Kuraray America, Incorporated
600 Lexington Avenue, 26th Floor
New York, New York 10022

FEB - 2 2007

Re: K063593
Trade/Device Name: CLEARFIL MAJESTY Flow
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: December 1, 2006
Received: December 11, 2006

Dear Mr. Nishida:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063593

Device Name: CLEARFIL MAJESTY Flow

Indications for Use:

CLEARFIL MAJESTY Flow is indicated for the following restorative applications:

- Direct restorations for anterior and posterior teeth (Class I – III, V cavities, cervical caries, root erosion)
- Cavity base / liner
- Intraoral repairs of fractured crowns / bridges / composite resin

Prescription Use ___x___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___N/A___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division Sign-Off
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K063593